Guidance on the Use of Concentration Ranges Pursuant to the *Hazardous Products Regulations*

Canada

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Introduction

An amendment to the *Hazardous Products Regulations* (HPR) came into force on April 4, 2018, permitting the use of prescribed concentration ranges for hazardous ingredients on safety data sheets if the actual concentration or actual concentration range of these ingredients are withheld as trade secrets. Pursuant to this amendment, certain subparts under "Part 4 Safety Data Sheet" of the Technical Guidance on the Requirements of the *Hazardous Products Act* and the *Hazardous Products Regulations* (Technical Guidance) are no longer up-to-date. These subparts are: the discussion of section 4.5 of the HPR (p.134), Appendix 3 – Guidance on the Disclosure of Ingredient Concentrations and Concentration Ranges on Safety Data Sheets (pp. 148-154) and Appendix 4 – Comparison of Ingredient Concentration Disclosure and CBI Protection Requirements (p. 155).

The intent of this document is to update the Technical Guidance to align with the 2018 HPR amendment and provide guidance on the current HPR subsections. This document replaces the discussion of section 4.5 of the HPR in the Technical Guidance with discussions of subsections 4.4.1(1), 4.4.1(2), 4.4.1(3), 4.4.1(4), 4.5(1), 4.5(2), 4.5(3) and 4.5(4) of the HPR. Appendix 1 and 2 of this document replace Appendix 3 and 4 of the Technical Guidance, respectively.

Note: In case of discrepancy between this document and the Acts or Regulations, the official versions of the Acts or Regulations will prevail.

This document contains references to legislation and guidance pertaining to other Competent Authorities, for example, the United States (U.S.) Occupational Safety and Health Administration's Hazard Communication Standard 2012 (HCS 2012). These references are often made for comparative purposes and, in that context, are based on Health Canada's understanding of the legislation and guidance. For compliance purposes and additional information regarding the legislation and guidance from other Competent Authorities referred to in this document, readers should consult the relevant Competent Authority.

Specific questions or comments regarding this guidance, including the Workplace Hazardous Materials Information System (WHMIS) and implementation of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) for workplace chemicals in Canada can be directed to Health Canada: hc.whmis-simdut.sc@canada.ca

Additional information can be found online:

- Health Canada's WHMIS webpage
- *Hazardous Products Act* (HPA)
- *Hazardous Products Regulations* (HPR)
- *Hazardous Materials Information Review Act* (HMIRA)
- *Hazardous Materials Information Review Regulations* (HMIRR)

Discussion of the *Hazardous Products Regulations* Subsection 4.4.1(1)

Concentration range – material or substance always present at the same concentration

4.4.1(1) If the concentration of a material or substance in a hazardous product is required to be provided on a safety data sheet and the material or substance is always present at the same concentration, the safety data sheet must provide

(a) the actual concentration of the material or substance in the hazardous product; or

(b) one of the concentration ranges set out in subsection (3) within which the actual concentration of the material or substance in the hazardous product falls.

Paragraph 3(2)(d) of Schedule 1 of the HPR specifies that the actual concentration of any hazardous ingredient in a hazardous product must be disclosed on the safety data sheet (SDS) if the hazardous ingredient is present:

- above the concentration limit designated for the category or subcategory of a health hazard class in which the hazardous ingredient is classified, or
- at a concentration that results in the product's classification in a category or subcategory of a health hazard class.

Paragraph 4.4.1(1)(a) of the HPR requires that the actual concentration of a material or substance in a hazardous product be provided on an SDS when that material or substance is always present at the same concentration.

However, paragraph 4.4.1(1)(b) allows a prescribed concentration range regarding that ingredient to be provided on the SDS in lieu of its actual concentration, if the actual concentration is withheld as a trade secret. The prescribed concentration ranges can be found in subsection 4.4.1(3) of the HPR.

Discussion of the *Hazardous Products Regulations* Subsection 4.4.1(2)

Actual concentration within more than one concentration range

4.4.1(2) For the purpose of paragraph (1)(b), if the actual concentration of a material or substance in a hazardous product falls within more than one of the concentration ranges set out in subsection (3), any one of those ranges may be provided on the safety data sheet.

If, for the purpose of protecting a trade secret, the actual concentration of a hazardous ingredient falls within more than one of the prescribed concentration ranges set out under subsection 4.4.1(3), then any one of the prescribed concentration ranges that the actual concentration falls within may be used on the SDS. For example, if the actual concentration of hazardous ingredient A in a mixture is 1.2%, and therefore falls into the prescribed concentration ranges 0.5 to 1.5% (paragraph 4.4.1(3)(b)) and 1 to 5% (paragraph 4.4.1(3)(c)), then either 0.5 to 1.5% or 1 to 5% can be provided on the SDS.

Discussion of the *Hazardous Products Regulations* Subsection 4.4.1(3)

Concentration ranges

4.4.1(3) For the purposes of paragraph (1)(b) and subsection (2), the concentration ranges are the following:

(a) from 0.1 to 1%;
(b) from 0.5 to 1.5%;
(c) from 1 to 5%;
(d) from 3 to 7%;
(e) from 5 to 10%;
(f) from 7 to 13%;
(g) from 10 to 30%;
(h) from 15 to 40%;
(i) from 30 to 60%;
(j) from 45 to 70%;
(k) from 60 to 80%;
(l) from 65 to 85%; and
(m) from 80 to 100%.

If, for the purpose of protecting a trade secret, a prescribed concentration range is provided on the SDS instead of the actual concentration of a hazardous ingredient, the ranges provided under subsection 4.4.1(3) can be used on the SDS.

If there is evidence that an ingredient at a concentration less than 0.1% contributes to a product being classified in a category or subcategory of any health hazard class, then the ingredient and its concentration must be disclosed on the SDS (refer to the discussion of Part 8 and Schedule I of the HPR in the Technical Guidance). However, if the actual concentration is less than 0.1% and considered to be a trade secret, the only way to protect this information is to file a claim for a confidential business information (CBI) exemption under the HMIRA (refer to the discussion of section 5.7 of the HPR in the Technical Guidance) as there are no prescribed concentration ranges for less than 0.1%.

Discussion of the *Hazardous Products Regulations* Subsection 4.4.1(4)

Statement – trade secret

4.4.1(4) If the safety data sheet provides a concentration range further to paragraph (1)(b), it must also provide, immediately following the concentration range, a statement to the effect that the actual concentration is withheld as a trade secret.

If the SDS provides a prescribed concentration range in order to withhold the actual concentration as a trade secret, a claim for a CBI exemption under the HMIRA does not need to be filed. A statement to the effect that the actual concentration is withheld as a trade secret must be provided on the SDS immediately following the prescribed concentration range. The expression "immediately following" could include the placement of an asterisk beside the prescribed concentration range that refers to a statement at the end of the list of ingredients. An example is provided in Appendix 2.

Further guidance on the disclosure of ingredient concentrations and concentration ranges on SDSs is provided in Appendix 1.

Appendix 2 provides a comparison of ingredient concentration disclosure and CBI protection requirements across WHMIS 1988, WHMIS 2015 and HCS 2012.

Discussion of the *Hazardous Products Regulations*
Subsection 4.5(1)

Concentration range — material or substance not always present at the same concentration

4.5(1) If the concentration of a material or substance in a hazardous product is required to be provided on a safety data sheet and the material or substance is not always present at the same concentration, the safety data sheet must provide

(a) the actual concentration range of the material or substance in the hazardous product;

(b) one of the concentration ranges set out in subsection (3) within which the actual concentration range of the material or substance in the hazardous product falls entirely; or

(c) if the actual concentration range of the material or substance in the hazardous product is equal to or greater than 0.1% but less than or equal to 30%, and the actual concentration range does not fall entirely within any of the concentration ranges set out in subsection (3), a concentration range that is created by combining two consecutive ranges from those set out in paragraphs (3)(a) to (g), provided that the combined concentration range does not include any range that falls entirely outside the actual concentration range in which the material or substance is present in the hazardous product.

As mentioned in the discussion of subsection 4.4.1(1), paragraph 3(2)(d) of Schedule 1 of the HPR specifies that the actual concentration of any hazardous ingredient in a hazardous product must be disclosed on the SDS if the hazardous ingredient is present:

- above the concentration limit designated for the category or subcategory of a health hazard class in which the hazardous ingredient is classified, or
- at a concentration that results in the product's classification in a category or subcategory of a health hazard class.

Furthermore, if the concentration required to be disclosed is not always present at the same concentration, the SDS must disclose the actual concentration range of that hazardous ingredient. However, a prescribed concentration range can be provided on the SDS in lieu of the actual concentration range, if the actual concentration range is a trade secret. The prescribed concentration ranges can be found in subsection 4.5(3) of the HPR.

Alternatively, if the actual concentration range does not fall entirely within a prescribed concentration range and the actual concentration range of the hazardous ingredient in the hazardous product is equal to or greater than 0.1% but less than or equal to 30%, a concentration range can be created by combining two consecutive prescribed concentration ranges. The combined concentration range can only be provided if it does not use a prescribed concentration range that falls entirely outside of the actual concentration range.

Prescribed concentration ranges are considered to be consecutive based on the order they are listed in the HPR (for example, paragraphs 4.5(3)(a) + (3)(b), paragraphs 4.5(3)(b) + (3)(c) or paragraphs 4.5(3)(c) + (3)(d) of the HPR). When combining consecutive prescribed concentrations, the most lower bound and upper bound concentration must be provided to form the range. For example, if the actual concentration range of hazardous ingredient A is 2.5 to 5.5%, the prescribed concentration ranges 1 to 5% (paragraph 5(3)(c)) and 3 to 7% (paragraph 5(3)(d)) can be combined to create a combined concentration range of 1 to 7% for hazardous ingredient A.

If the actual concentration range of a hazardous ingredient spans over more than two consecutive prescribed concentration ranges, there are two options: submit a claim for a CBI exemption under the HMIRA (refer to the discussion of section 5.7 of the HPR in the Technical Guidance), or provide the actual concentration range on the SDS. For example, if the actual concentration range is 4 to 18% and is to be withheld as a trade secret, a claim for a CBI exemption would need to be filed under the HMIRA.

Discussion of the *Hazardous Products Regulations*
Subsection 4.5(2)

Actual concentration range within more than one concentration range

4.5(2) For the purposes of paragraph (1)(b), if the actual concentration range of a material or substance in a hazardous product falls entirely within more than one of the concentration ranges set out in subsection (3), any one of those ranges may be provided on the safety data sheet.

If, for the purpose of protecting a trade secret, the actual concentration range of a hazardous ingredient falls entirely within more than one of the prescribed concentration ranges, any one of the prescribed concentration ranges that the actual concentration range falls entirely within may be provided on the SDS. For example, if the actual concentration range of hazardous ingredient A in a mixture is 30 to 40%, and therefore falls into the prescribed concentration ranges 15 to 40% (paragraph 5(3)(h)) and 30 to 60% (paragraph 5(3)(i)), then either 15 to 40% or 30 to 60% can be provided on the SDS.

Discussion of the *Hazardous Products Regulations* Subsection 4.5(3)

Concentration ranges

4.5(3) For the purposes of paragraphs (1)(b) and (c) and subsection (2), the concentration ranges are the following:

(a) from 0.1 to 1%;
(b) from 0.5 to 1.5%;
(c) from 1 to 5%;
(d) from 3 to 7%;
(e) from 5 to 10%;
(f) from 7 to 13%;
(g) from 10 to 30%;
(h) from 15 to 40%;
(i) from 30 to 60%;
(j) from 45 to 70%;
(k) from 60 to 80%;
(l) from 65 to 85%; and
(m) from 80 to 100%.

If, for the purpose of protecting a trade secret, a prescribed concentration range is provided on the SDS instead of the actual concentration range of a hazardous ingredient, the ranges provided under subsection 4.5(3) can be used on the SDS.

As mentioned in the discussion of subsection 4.4.1(3), if there is evidence that an ingredient at a concentration less than 0.1% contributes to a product being classified in a category or subcategory of any health hazard class, then the ingredient and its concentration must be disclosed on the SDS (refer to the discussion of Part 8 and Schedule I of the HPR in the Technical Guidance). However, if the actual concentration range spans less than 0.1% and is considered to be a trade secret, the only way to protect this information is to file a claim for a CBI exemption under the provisions of the HMIRA (refer to the discussion of section 5.7 of the HPR in the Technical Guidance), as there are no prescribed concentration ranges for less than 0.1%.

Discussion of the *Hazardous Products Regulations* Subsection 4.5(4)

Statement — trade secret

4.5(4) If the safety data sheet provides a concentration range further to paragraph (1)(b) or (c), it must also provide, immediately following that concentration range, a statement to the effect that the actual concentration range is withheld as a trade secret.

If the SDS provides a prescribed concentration range in order to withhold the actual concentration range as a trade secret, a claim for a CBI exemption under the HMIRA does not need to be filed. A statement to the effect that the actual concentration range is withheld as a trade secret must be provided on the SDS. The expression “immediately following” could include the placement of an asterisk beside the prescribed concentration range that refers to a statement at the end of the list of ingredients. An example is provided in Appendix 2.

Further guidance on the disclosure of ingredient concentrations and concentration ranges on SDSs is provided in Appendix 1.

Appendix 2 provides a comparison of ingredient concentration disclosure and CBI protection requirements across WHMIS 1988, WHMIS 2015 and HCS 2012.

The following sources were consulted in the development of this guidance document:

- 29 CFR 1910.1200, Hazard Communication
- *Hazardous Materials Information Review Act*, R.S.C. 1985, c. 24 (3rd Supp.), Part III
- *Hazardous Products Act*, R.S.C., 1985, c. H-3
- *Hazardous Products Regulations*, SOR/2015-17
- United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Fifth revised edition, 2013.

Appendix 1 – Guidance on the Disclosure of Ingredient Concentrations and Concentration Ranges on Safety Data Sheets

Appendix 1 replaces Appendix 3 to part 4 of the Technical Guidance.

Background

On February 11, 2015, the Government of Canada published in the *Canada Gazette*, Part II, the HPR which, in addition to the amendments made to the HPA, modified WHMIS to incorporate the United Nations GHS for work place chemicals. The *Controlled Products Regulations* (CPR) and the Ingredient Disclosure List of the original WHMIS 1988 were repealed and replaced by the HPR. The WHMIS requirements of the amended HPA and the HPR are referred to as WHMIS 2015.

Through the publication of the new HPR, Canada fulfilled a key commitment under the Canada-U.S. Regulatory Cooperation Council (RCC) to "align and synchronize implementation of common classification and labelling requirements for work place chemicals... without reducing the level of safety or of protection to workers". The GHS provides an international standard for the classification and communication of information on hazardous products, and includes new harmonized criteria for hazard classification and requirements for labels and SDSs.

A key objective of the implementation of the GHS was to create a system that allows Canadian and U.S. requirements to be met through the use of a single label and SDS for each hazardous product.

An amendment to the HPR came into force on April 4, 2018, which allows for the use of a prescribed concentration range pertaining to any hazardous ingredient on the SDS if the actual concentration or actual concentration range of that ingredient is withheld as a trade secret. This amendment provides regulated parties with a means to protect the actual concentration or actual concentration range of a hazardous ingredient without having to file a claim for a CBI exemption under the HMIRA.

Ingredient Disclosure, Concentrations and Concentration Ranges

The HPR and the U.S. HCS 2012 require suppliers to provide information on hazards and safe use, handling and storage of a hazardous product on the SDS and label associated with that product. A product's SDS must disclose all hazardous ingredients in the product, its toxicological properties, any safety precautions workers need to take when using, handling and storing the product, and first aid treatment required in the case of exposure, along with other information specified in Schedule 1 of the HPR.

The following is a comparison of current Canadian and U.S. requirements for ingredient disclosure, concentrations and concentration ranges. This information also includes previous CPR requirements, and the HPA requirements prior to the February 11, 2015 amendment.

Regulatory System: Canada WHMIS 1988
(repealed CPR)

The criteria with regard to ingredient disclosure, including which ingredients of a mixture need to be disclosed, were set out in subparagraphs 13(a)(i) to (iv) of the HPA prior to the coming into force of its amendments on February 11, 2015.

Former subsections 11(2) and (3) of the CPR (Range of Concentration of Ingredients)

11(2) Where the concentration of an ingredient of a controlled product or a complex mixture that is a component of a controlled product is required to be disclosed on a material safety data sheet and the ingredient or complex mixture is not always present in the same concentration in the controlled product, the material safety data sheet may disclose, in lieu of the actual concentration of the ingredient or complex mixture, that the ingredient or complex mixture falls within one of the ranges of concentration set out in subsection (3), where the actual concentration of the ingredient or complex mixture falls within that range.

(3) For the purposes of subsection (2), the ranges of concentration are the following:

(a) from 0.1 to 1 per cent;
(b) from 0.5 to 1.5 per cent;
(c) from 1 to 5 per cent;
(d) from 3 to 7 per cent;
(e) from 5 to 10 per cent;
(f) from 7 to 13 per cent;
(g) from 10 to 30 per cent;
(h) from 15 to 40 per cent;
(i) from 30 to 60 per cent;
(j) from 40 to 70 per cent; and
(k) from 60 to 100 per cent.

Regulatory System: Canada WHMIS 2015 (HPR)
(came into force on February 11, 2015 and was amended on April 4, 2018)

Section 4.4.1 of the HPR:

Concentration range – material or substance always present at the same concentration

(1) If the concentration of a material or substance in a hazardous product is required to be provided on a safety data sheet and the material or substance is always present at the same concentration, the safety data sheet must provide

(a) the actual concentration of the material or substance in the hazardous product; or
(b) one of the concentration ranges set out in subsection (3) within which the actual concentration of the material or substance in the hazardous product falls.

Actual concentration within more than one concentration range

(2) For the purpose of paragraph (1)(b), if the actual concentration of a material or substance in a hazardous product falls within more than one of the concentration ranges set out in subsection (3),

any one of those ranges may be provided on the safety data sheet.

Concentration ranges

(3) For the purposes of paragraph (1)(b) and subsection (2), the concentration ranges are the following:

(a) from 0.1 to 1%;
(b) from 0.5 to 1.5%;
(c) from 1 to 5%;
(d) from 3 to 7%;
(e) from 5 to 10%;
(f) from 7 to 13%;
(g) from 10 to 30%;
(h) from 15 to 40%;
(i) from 30 to 60%;
(j) from 45 to 70%;
(k) from 60 to 80%;
(l) from 65 to 85%; and
(m) from 80 to 100%.

Statement — trade secret

(4) If the safety data sheet provides a concentration range further to paragraph (1)(b), it must also provide, immediately following the concentration range, a statement to the effect that the actual concentration is withheld as a trade secret.

Section 4.5 of the HPR:

Concentration range — material or substance not always present at the same concentration

(1) If the concentration of a material or substance in a hazardous product is required to be provided on a safety data sheet and the material or substance is not always present at the same concentration, the safety data sheet must provide

(a) the actual concentration range of the material or substance in the hazardous product;
(b) one of the concentration ranges set out in subsection (3) within which the actual concentration range of the material or substance in the hazardous product falls entirely; or
(c) if the actual concentration range of the material or substance in the hazardous product is equal to or greater than 0.1% but less than or equal to 30%, and the actual concentration range does not fall entirely within any of the concentration ranges set out in subsection (3), a concentration range that is created by combining two consecutive ranges from those set out in paragraphs (3)(a) to (g), provided that the combined concentration range does not include any range that falls entirely outside the actual concentration range in which the material or substance is present in the hazardous product.

Actual concentration range within more than one concentration range

(2) For the purposes of paragraph (1)(b), if the actual concentration range of a material or substance in a hazardous product falls entirely within more than one of the concentration ranges

set out in subsection (3), any one of those ranges may be provided on the safety data sheet.

Concentration ranges

(3) For the purposes of paragraphs (1)(b) and (c) and subsection (2), the concentration ranges are the following:

(a) from 0.1 to 1%;
(b) from 0.5 to 1.5%;
(c) from 1 to 5%;
(d) from 3 to 7%;
(e) from 5 to 10%;
(f) from 7 to 13%;
(g) from 10 to 30%;
(h) from 15 to 40%;
(i) from 30 to 60%;
(j) from 45 to 70%;
(k) from 60 to 80%;
(l) from 65 to 85%; and
(m) from 80 to 100%.

Statement — trade secret

(4) If the safety data sheet provides a concentration range further to paragraph (1)(b) or (c), it must also provide, immediately following that concentration range, a statement to the effect that the actual concentration range is withheld as a trade secret.

Section 3 of Schedule 1 of the HPR (Information Elements on Safety Data Sheet)

(1) In the case of a hazardous product that is a material or substance,

(a) its chemical name;
(b) its common name and synonyms;
(c) its CAS registry number and any unique identifiers; and
(d) the chemical name of the impurities, stabilizing solvents and stabilizing additives that are known to the supplier, that individually are classified in any category or subcategory of a health hazard class and that contribute to the classification of the material or substance

(2) In the case of a hazardous product that is a mixture, for each material or substance in the mixture that, individually, is classified in any category or subcategory of a health hazard class and is present above the concentration limit that is designated for the category or subcategory in which it is classified or is present in the mixture at a concentration that results in the mixture being classified in a category or subcategory of any health hazard class,

(a) its chemical name;
(b) its common name and synonyms;
(c) its CAS registry number and any unique identifiers; and
(d) its concentration.

Regulatory System: U.S. HCS 2012

Under item 3 of Table D.1 (Minimum Information for an SDS) – Except as provided for in paragraph (i) of §1910.1200 on trade secrets:

For Substances

(a) Chemical name;
(b) Common name and synonyms;
(c) CAS number and other unique identifiers;
(d) Impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance.

For Mixtures

In addition to the information required for substances:

(a) The chemical name and concentration (exact percentage) or concentration ranges of all ingredients which are classified as health hazards in accordance with paragraph (d) of §1910.1200 and
    (1) are present above their cut-off/concentration limits; or
    (2) present a health risk below the cut-off/ concentration limits.
(b) The concentration (exact percentage) shall be specified unless a trade secret claim is made in accordance with paragraph (i) of §1910.1200, when there is batch-to-batch variability in the production of a mixture, or for a group of substantially similar mixtures (See A.0.5.1.2) with similar chemical composition. In these cases, concentration ranges may be used.

For All Chemicals Where a Trade Secret is Claimed

Where a trade secret is claimed in accordance with paragraph (i) of §1910.1200, a statement that the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret is required.

Appendix 2 provides a comparison of ingredient concentration disclosure and CBI protection requirements across WHMIS 1988, WHMIS 2015 and HCS 2012. These requirements are discussed in further detail below.

Changes Made from WHMIS 1988 to WHMIS 2015 Regarding Concentration Ranges

Under WHMIS 1988, the CPR permitted the use of concentration ranges when ingredients were not always present at the same concentration in a controlled product. A set of prescribed concentration ranges was listed in subsection 11(3) of the CPR, as specified in the previous section on Ingredient Disclosure, Concentrations and Concentration Ranges. When the CPR was repealed to be replaced with the HPR, ingredients had to be disclosed in their actual concentration or actual concentration range. An amendment to the HPR, which came into force on April 4, 2018, once again permits the use of prescribed concentration ranges in certain cases.

Sections 4.4.1 and 4.5 of the HPR specify that, where a hazardous ingredient is required to be disclosed, the **actual concentration** of the ingredient, or, the **actual concentration range** of the ingredient if the hazardous ingredient is not always present in the hazardous product at the same concentration, must be disclosed. However, a prescribed concentration range may be provided on the SDS instead of the actual concentration or actual concentration range of the hazardous ingredient if either of the latter is withheld as a trade secret. If a prescribed concentration range is provided, then a statement to the effect that the actual concentration or actual concentration range has been withheld as a trade secret is required. The prescribed concentration ranges (a) through (i) in the HPR remain identical to that of the CPR, while the prescribed concentration ranges (j) through (m) provide narrower ranges at higher concentrations in the HPR.

Terminology - WHMIS 2015 and HCS 2012 (United States)

The HPR and the HCS 2012 are aligned with regard to what is meant by "**concentration**" (HPR) versus "**concentration (exact percentage)**" (HCS 2012). For the purposes of this Appendix and Appendix 2, the term "**true concentration**" is used as a single term to represent the concentration as it is required to be disclosed by WHMIS 2015 and HCS 2012 (in other words, in place of their respective terms, "concentration" and "concentration (exact percentage)").

Under the HPR, the concentration of a hazardous ingredient in a mixture may either be expressed:

- as a percentage, with the type of units specified (for example, 5.0% weight/volume), or
- as a unit of measurement (for example, 5.0 g/l).

When a concentration is expressed as a percentage, the exact percentage of the hazardous ingredient in the mixture must be disclosed. Similarly, when a concentration is expressed as a unit of measurement, the exact concentration must be disclosed. The HCS 2012 has the same requirement with regard to "concentration (exact percentage)".

The HPR and the HCS 2012 are also aligned with regard to what is meant by "**actual concentration range**" (HPR) and "**concentration range**" (HCS 2012):

- In the HPR, the term "**actual concentration range**" refers to the range of concentrations within which the true concentration of a hazardous ingredient in a mixture would be expected to fall, given the quality control parameters of the manufacturing process for the mixture.
- The HCS 2012 uses the term "**concentration range**", which has the same meaning.

For the purposes of this Appendix and Appendix 2, the term "**true concentration range**" is used as a single term to represent the concentration range as it is required to be disclosed by WHMIS 2015 and HCS 2012 (in other words, in place of their respective terms, "actual concentration range" and "concentration range").

Disclosing an Ingredient Concentration or Concentration Range

Under both the HPR and HCS 2012:

- The **true concentration** of a hazardous ingredient must be disclosed when the ingredient is present in the mixture at a fixed concentration.

- When a hazardous ingredient is not always present at the same concentration, then the **true concentration range** of the ingredient in the mixture must be disclosed.

When disclosing a true concentration range, the following conditions apply:

- The ingredient must be present in the mixture at a range of concentrations.
- The range must accurately reflect the concentration variation.
- The hazard classification must accurately reflect the hazards associated with the mixture.

The concentration of a hazardous ingredient in a mixture may vary due to batch-to-batch variability. In these situations, a supplier must comply with section 4.5 of the HPR to disclose the true concentration range of the hazardous ingredient, unless the suppliers withholds that concentration range as a trade secret and discloses instead one of the prescribed concentration ranges specified in that section.

This requirement differs from the provision in the HCS 2012, in that the HCS does not allow true concentration ranges to be withheld as trade secrets.

Batch-to-batch variability

"Batch-to-batch variability" refers to situations where products are produced to specified criteria, but product composition varies from batch to batch. Variations in product composition could be due to factors such as production tolerances (fluctuations permitted by the quality control parameters of the manufacturing process) and varying concentrations of starting materials.

Example: If the manufacturing formula for a mixture calls for 10% of hazardous ingredient A, but due to batch-to-batch variability, the true concentration is expected to vary from 8 to 12%, then the supplier must disclose 8 to 12% as the true concentration range, unless the supplier discloses one of the prescribed concentration ranges specified in section 4.5.

When a true concentration range is disclosed, SDSs must be in compliance with requirements in the HPR for hazard classification (section 2.6) and information disclosed on SDSs (section 4.4). Section 2.6 states that "… the maximum concentration must be used for the purposes of establishing whether the mixture is classified in a category or subcategory of a health hazard class". Thus, in the example provided above, where the concentration of ingredient A ranges from 8 to 12% due to batch-to-batch variability, the classification of the mixture with respect to the health hazard classes must be based on the maximum concentration of 12%.

Section 4.4 states that "…the information provided on the safety data sheet must be based on data available that correspond to the most hazardous concentration of each ingredient in the mixture, whether those data pertain to an ingredient or the mixture as a whole". Thus the hazard classification and the health and safety information provided on the SDS must be reflective of the highest degree of hazard that the mixture could present.

Furthermore, when a prescribed concentration range is disclosed, SDSs must also be in compliance with sections 2.6 and 4.4. For example, where the true concentration range of ingredient A varies from 4 to 6% due to batch-to-batch variability and the supplier elects to withhold the true concentration range of that ingredient as a trade secret and uses instead the prescribed concentration range of 3 to 7% (paragraph 4.5(3)(d)), the classification of the mixture with respect to the health hazard classes must be based on the (true) maximum concentration of 6%, not 7%.

The obligation to disclose the true concentration range applies regardless of the magnitude of the true concentration range. For example, where the true concentration variation range of a hazardous ingredient is from 10 to 20%, that range must also be disclosed on the SDS. Similarly, sections 2.6 and 4.4.of the HPR apply to any true concentration range, regardless of its magnitude. Maintaining documentation on the manufacturing process which demonstrates product composition variability is important to support the disclosure of any true concentration range.

Protection of Confidential Business Information

Canada and the U.S. are aligned with regard to requirements for hazardous ingredient disclosure on SDSs, but the mechanisms to protect CBI are different. In Canada, a supplier must file a claim for a CBI exemption with Health Canada under the HMIRA to request an exemption from the requirement under the HPA and HPR to disclose specific information that the claimant considers to be CBI, such as the chemical name or the name of a toxicological study that identifies a hazardous ingredient. A supplier can use a prescribed concentration range from the HPR to withhold the true concentration or true concentration range of a hazardous ingredient, in lieu of filing a claim under the HMIRA, if all relevant provisions of the HPR are met, including a statement to the effect the true concentration or true concentration range has been withheld as a trade secret. In the U.S., the specific chemical identity and/or concentration (exact percentage) of a hazardous ingredient may be claimed as a trade secret in accordance with paragraph (i) of the HCS 2012 and there is no government review process.

When a claim for a CBI exemption is filed with Health Canada under the HMIRA to protect only the chemical name of a hazardous ingredient, the supplier must include in the SDS:

- the true concentration or true concentration range of that ingredient,
- a statement to indicate that a claim was filed, and
- the date of filing and the claim registry number assigned to the claim under the HMIRA.

Once the claim has been approved by Health Canada, the SDS must indicate that an exemption has been granted, the date of the decision granting the exemption and the claim registry number assigned to the claim under the HMIRA.

The following sources were consulted in the development of this guidance document:

- 29 CFR 1910.1200, Hazard Communication
- *Hazardous Materials Information Review Act*, R.S.C. 1985, c. 24 (3rd Supp.), Part III
- *Hazardous Products Act*, R.S.C., 1985, c. H-3
- *Hazardous Products Regulations*, SOR/2015-17
- United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Fifth revised edition, 2013.

Appendix 2 – Comparison of Ingredient Concentration Disclosure and CBI Protection Requirements

Appendix 2 replaces Appendix 4 to part 4 of the Technical Guidance.

Table 1 provides a comparison of ingredient concentration disclosure and CBI protection requirements for SDS under the historical Canadian regulatory system (WHMIS 1988), the current Canadian regulatory system (WHMIS 2015, prior to and after the 2018 HPR amendment) and the U.S.'s regulatory system (HCS 2012).

Table 1. Comparison of ingredient concentration disclosure and CBI protection requirements under WHMIS 1988, WHMIS 2015 and HCS 2012, with an example ingredient true concentration of 17% for toluene and an example ingredient true concentration range of 32-41% for acetone.

No CBI or CBI protection	Concentration or Concentration Range	Regulatory System			
		WHMIS 1988 (WHMIS before GHS)	**WHMIS 2015 (GHS in Canada)**	**WHMIS 2015 with 2018 amendment to the HPR (GHS in Canada)**	**HCS 2012 (GHS in U.S.)**
No CBI	**Concentration** (where concentration does not vary)	True Concentration **Chemical name** / **Volume %** Toluene 17%	True Concentration **Chemical name** / **Volume %** Toluene 17%	True Concentration **Chemical name** / **Volume %** Toluene 17%	True Concentration **Chemical name** / **Volume %** Toluene 17%
	Concentration Range (where concentration varies, e.g. batch-to-batch variability)	Standardized Concentration Range **Chemical name** / **Volume %** Acetone 30-60%	True Concentration Range **Chemical name** / **Volume %** Acetone 32-41%	True Concentration Range **Chemical name** / **Volume %** Acetone 32-41%	True Concentration Range **Chemical name** / **Volume %** Acetone 32-41%
CBI Protection	**Concentration** (where concentration does not vary)	"Trade Secret" and CBI Registry Number (Range Optional) **Chemical name** / **Volume %** Toluene Trade Secret* *HMIRA claim filed June 1, 2015, RN: 5555	"Trade Secret" and CBI Registry Number (Range Optional) **Chemical name** / **Volume %** Toluene Trade Secret* *HMIRA claim filed June 1, 2015, RN: 5555	"Trade Secret", Prescribed Concentration Range** **Chemical name** / **Volume %** Toluene 10-30%* *Actual concentration trade secret	"Trade Secret" (Range Optional) **Chemical name** / **Volume %** Toluene Trade Secret
	Concentration Range (where concentration varies, e.g. batch-to-batch variability)	"Trade Secret" and CBI Registry Number **Chemical name** / **Volume %** Acetone Trade Secret* *HMIRA claim filed June 1, 2015, RN: 5555	"Trade Secret" and CBI Registry Number **Chemical name** / **Volume %** Acetone Trade Secret* *HMIRA claim filed June 1, 2015, RN: 5555	"Trade Secret", Prescribed Concentration Range** **Chemical name** / **Volume %** Acetone 30-60%* *Actual concentration range trade secret	**CBI Claim Not Allowed Supplier must disclose True Concentration Range** **Chemical name** / **Volume %** Acetone 32-41%

Alignment of Canada / U.S. Requirements

Aligned | Distinct But Complementary | Not Aligned

Volume % True Concentration / True Concentration Range Disclosed

Volume % CBI Protected

**Alternatively, a CBI claim under HMIRA can be filed and the ingredient concentration can be disclosed as shown under WHIMIS 2015, prior to the 2018 amendment.